

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference DCW/SH	<b>FOR FURTHER ACTION</b>		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB99/03392	International filing date (day/month/year) 13/10/1999	Priority date (day/month/year) 13/10/1998	
International Patent Classification (IPC) or national classification and IPC A61M1/00			
Applicant KCI MEDICAL LIMITED et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  02/05/2000	Date of completion of this report  22.01.2001
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Fontenay, P  Telephone No. +49 89 2399 2646  

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB99/03392

## I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

### Description, pages:

1-7 as originally filed

### Claims, No.:

1-11 as originally filed

### Drawings, sheets:

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB99/03392

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims	1-7
	No:	Claims	8-11
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-7
Industrial applicability (IA)	Yes:	Claims	1-11
	No:	Claims	

### 2. Citations and explanations **see separate sheet**

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB99/03392

**Re Item V** Reasoned statement under Article 35.2 with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 = WO-A-9718007

D2 = US-A-5669892

D2 was not cited in the International Search Report.

**V.1** The subject-matter of claims 8-11 is not new in the sense of Article 33(2) PCT.

V.1.1 Document D1 discloses an apparatus for applying negative pressure therapy to a wound site (see D1, page 1, lines 2 and 3). Said apparatus comprises an open celled foam pad (102) for application to the wound (see D1, page 9, third paragraph); a suction tube connecting the foam pad to a collection canister (100) and a tube (103) for connecting the canister to a pump (6) (see D1, page 5, lines 17-26). It is also noted that said means for connecting to a pump are also adapted for connecting to a wall suction point or a vacuum bottle by eventually providing the appropriate connecting tubes. The apparatus disclosed in D1 also comprises means (105) for sensing when the canister is full (see D1, page 6, second paragraph).

All the features of claim 8 are known in combination from D1. Claim 8 is therefore not new.

V.1.2 The apparatus of D1 further includes means for giving a warning that the canister is full (claim 9 - see D1, page 6, second paragraph). Means for monitoring the pressure at the wound site are also foreseen in D1 (claim 10 - see D1, page 5, lines 24-26). The pressure between canister and the suction source can also be regulated (claim 11 - see D1, page 5, lines 25-26).

The subject-matter of claims 9-11 is therefore also not new.

**V.2** The subject-matter of claims 1-7 is not inventive in the sense of Article 33(3) PCT.

V.2.1 In addition to the features mentioned under point V.1, the apparatus disclosed in D1 also comprises a pressure detecting means (105) connected to the suction tube (103) between the foam pad and the canister for indicating when the pressure in the suction tube falls below a predetermined level (see comments under point VIII).

The subject-matter of claim 1 accordingly differs from said known apparatus only in that the canister includes a shut-off valve which closes the outlet of the canister when it is full.

The problem to be solved by said features is to provide an alternative to the apparatus disclosed in D1 in which the working of the pump is automatically shut off.

It is however considered that it is common practise in hospitals today to associate suction lines with shut-off valves in order to avoid contamination of the hospital suction systems. The skilled man would accordingly incorporate a shut-off valve in his apparatus if he intends to connect it to an external suction line, without exercising any inventive skills. The applicant may for example refer to document D2, column 1, lines 31-39.

The subject-matter of claim 1 is therefore not inventive.

V.2.2 The features of dependent claims 2-7 are disclosed in relation with similar wound suction apparatuses known from the prior art as indicated in the International Search Report. It would accordingly be obvious for the skilled man to consider the teaching of said documents and to incorporate said features to the device of D1. The applicant may refer to the Guidelines, PCT/GL/3, § 8.8(B1)).

The dependent claims 2-7 therefore do not appear to contain any additional features which, in combination with the features of claim 1 to which they refer, involve an inventive step.

**Re Item VII** Certain defects in the international application

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB99/03392

- VII.1** Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D2 is not mentioned in the description, nor is this document identified therein.
- VII.2** Independent claim 1 should have been drafted in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would have been appropriate.
- VII.3** The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- VII.5** The application documents should be self-contained. The applicant should refer to the Guidelines PCT/GL/3, Chapter II, § 4.17. In present case, the wording "incorporated therein" as it appears on page 5, line 5 should have been deleted.
- VII.6** The reference to a non published application on page 5, line 4 should have been replaced by a reference to the corresponding publication number or deleted if such a publication does not exist.
- VII.7** Reference in claim 6 to claim 6 should have been corrected. Reference to relief valve "24" on page "6" should probably have been replaced by a reference to relief valve "11". Reference "15" should have been deleted on page 6, line 7 since said reference could not be found in the drawings.

**Re Item VIII** Certain observations on the international application

- VIII.1** The subject-matter of claim 1 is not clearly defined (Article 6 PCT).

The wording "for indicating when the pressure in the suction tube falls below a predetermined level" is ambiguous because it suggests that the pressure drops whereas according to the description, the pressure increases and tends to reach the atmospheric pressure. The applicant should have clearly defined that the relative negative pressure is meant.

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>DCW/SH</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, Item 5 below.	
International application No. <b>PCT/GB 99/ 03392</b>	International filing date (day/month/year) <b>13/10/1999</b>	(Earliest) Priority Date (day/month/year) <b>13/10/1998</b>
Applicant  <b>KCI MEDICAL LIMITED et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (see Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1  
☐ None of the figures.

## INTERNATIONAL SEARCH REPORT

International Application No.

GB 99/03392

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M1/00 A61M27/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 05873 A (MEDISCUS PROD LTD ; HEATON KEITH PATRICK (GB); LINA CESAR Z (US); K) 29 February 1996 (1996-02-29) page 7, paragraph 4 page 11, paragraph 4 -page 12, paragraph 1 page 16, paragraph 4 -page 17, paragraph 2 page 18, paragraph 4 -page 19, paragraph 1 figures 5,6,9	8-11
A	—	1,2,4-7
X	WO 97 18007 A (KCI MEDICAL LTD ; HEATON KEITH PATRICK (GB); HUNT KENNETH WILLIAM (GB) 22 May 1997 (1997-05-22) cited in the application page 5, paragraph 4 -page 6, paragraph 3 figure 1	8-11
A	—	1,3,4
	— / —	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"Z" document member of the same patent family

Date of the actual completion of the international search

2 February 2000

Date of mailing of the international search report

09/02/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
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Authorized officer

Lakkis, A



## INTERNATIONAL SEARCH REPORT

International Application No.

GB 99/03392

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 636 643 A (ARGENTA LOUIS C ET AL) 10 June 1997 (1997-06-10) column 5, line 43 - line 44 column 8, line 20 -column 9, line 52 figures 1,7-9	8,9,11
A	—	1,2
A	GB 2 235 877 A (TALLURI ANTONIO) 20 March 1991 (1991-03-20) page 4, line 21 -page 6, line 23	1,2,5,6, 8,9,11
A	DE 197 22 075 C (FLEISCHMANN WILHELM DR MED) 1 October 1998 (1998-10-01) column 4, line 15 - line 29 figure 1	1,10

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

GB 99/03392

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9605873	A	29-02-1996	AT 172377 T	15-11-1998
			AU 698477 B	29-10-1998
			AU 3349995 A	14-03-1996
			CA 2198243 A	29-02-1996
			DE 69505545 D	26-11-1998
			DE 69505545 T	11-03-1999
			EP 0777504 A	11-06-1997
			EP 0853950 A	22-07-1998
			JP 10504484 T	06-05-1998
			ZA 9506968 A	29-03-1996
WO 9718007	A	22-05-1997	CA 2237606 A	22-05-1997
			DE 19681649 T	03-12-1998
			DE 29623482 U	23-07-1998
			EP 0865304 A	23-09-1998
			GB 2307180 A	21-05-1997
			GB 2336546 A	27-10-1999
US 5636643	A	10-06-1997	US 5645081 A	08-07-1997
			AU 696031 B	27-08-1998
			AU 6360894 A	26-09-1994
			CA 2157772 A	15-09-1994
			EP 0688189 A	27-12-1995
			JP 9503923 T	22-04-1997
			WO 9420041 A	15-09-1994
			AT 164055 T	15-04-1998
			AU 674837 B	16-01-1997
			AU 3130393 A	15-06-1993
			CA 2121688 A	27-05-1993
			DE 9219136 U	18-06-1998
			DE 69224847 D	23-04-1998
			DE 69224847 T	20-08-1998
			EP 0620720 A	26-10-1994
			ES 2114956 T	16-06-1998
			JP 7501958 T	02-03-1995
			WO 9309727 A	27-05-1993
GB 2235877	A	20-03-1991	NONE	
DE 19722075	C	01-10-1998	EP 0880953 A	02-12-1998

# PATENT COOPERATION TREATY

Dow

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From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

## PCT

WOODCRAFT, David C.  
BROOKES & MARTIN  
High Holborn House  
52/54 High Holborn  
London WC1V 6SE  
GRANDE BRETAGNE

**RECEIVED**  
 24 JAN 2001  
**BROOKES & MARTIN**

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT  
(PCT Rule 71.1)

Date of mailing (day/month/year) 22.01.2001	
Applicant's or agent's file reference DCW/SH	<b>IMPORTANT NOTIFICATION</b>
International application No. PCT/GB99/03392	International filing date (day/month/year) 13/10/1999
Priority date (day/month/year) 13/10/1998	
Applicant KCI MEDICAL LIMITED et al.	

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Ullrich, C  Tel. +49 89 2399-2322
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The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:

IPEA/ EPO

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# PCT

## CHAPTER II

### DEMAND

under Article 31 of the Patent Cooperation Treaty:  
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only	
Identification of IPEA	Date of receipt of DEMAND
<b>Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION</b>	
Applicant's or agent's file reference DCW/VSU	
International application No. PCT/GB99/03392	International filing date (day/month/year) 13 October 1999
(Earliest) Priority date (day/month/year) 13 October 1998	
Title of invention NEGATIVE PRESSURE THERAPY USING WALL SUCTION	
<b>Box No. II APPLICANT(S)</b>	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
KCI MEDICAL LIMITED TWO RIVERS STATION LANE WITNEY OXFORDSHIRE OX8 6BH	
Telephone No.:	
Facsimile No.:	
Teleprinter No.:	
State (that is, country) of nationality: GB	State (that is, country) of residence: GB
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
HUNT, Kenneth William 18 Egdon Drive Merley Wimboume Dorset BH21 1TY	
State (that is, country) of nationality: GB	State (that is, country) of residence: GB
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
HEATON, Keith Patrick 33 Hermitage Road Poole Dorset BH14 OQG	
State (that is, country) of nationality: GB	State (that is, country) of residence: GB
<input type="checkbox"/> Further applicants are indicated on a continuation sheet.	

**Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE**The following person is ☒ agent ☐ common representativeand ☐ has been appointed earlier and represents the applicant(s) also for international preliminary examination.☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.Name and address: *(Family name followed by given name; for a legal entity, full official designation.  
The address must include postal code and name of country.)*WOODCRAFT, David Charles  
BROOKES & MARTIN  
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52/54 High Holborn  
London WC1V 6SE  
GB

Telephone No.:

020 7242 9631

Facsimile No.:

020 7831 0586

Teleprinter No.:

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.**Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION****Statement concerning amendments: \***

1. The applicant wishes the international preliminary examination to start on the basis of:

☒ the international application as originally filedthe description ☐ as originally filed☐ as amended under Article 34the claims ☐ as originally filed☐ as amended under Article 19 (together with any accompanying statement)☐ as amended under Article 34the drawings ☐ as originally filed☐ as amended under Article 342. ☐ The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.3. ☐ The applicant wishes the start of the international preliminary examination to be postponed until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

\* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

**Language for the purposes of international preliminary examination:**☐ which is the language in which the international application was filed.☐ which is the language of a translation furnished for the purposes of international search.☐ which is the language of publication of the international application.☐ which is the language of the translation (to be) furnished for the purposes of international preliminary examination.**Box No. V ELECTION OF STATES**The applicant hereby elects all eligible States *(that is, all States which have been designated and which are bound by Chapter II of the PCT)*

excluding the following States which the applicant wishes not to elect:

**Box No. VI CHECK LIST**

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- |  |   |        |
|--|---|--------|
| 1. translation of international application                              | : | sheets |
| 2. amendments under Article 34   | : | sheets |
| 3. copy (or, where required, translation) of amendments under Article 19 | : | sheets |
| 4. copy (or, where required, translation) of statement under Article 19  | : | sheets |
| 5. letter  | : | sheets |
| 6. other ( <i>specify</i> )  | : | sheets |

For International Preliminary Examining Authority use only

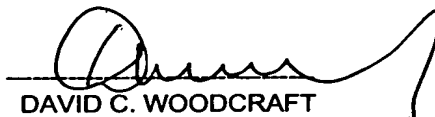
received	not received
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

The demand is also accompanied by the item(s) marked below:

- |  |   |
|--|---|
| 1. <input checked="" type="checkbox"/> fee calculation sheet                             | 4. <input type="checkbox"/> statement explaining lack of signature                                  |
| 2. <input type="checkbox"/> separate signed power of attorney                            | 5. <input type="checkbox"/> nucleotide and or amino acid sequence listing in computer readable form |
| 3. <input type="checkbox"/> copy of general power of attorney, reference number, if any: | 6. <input type="checkbox"/> other ( <i>specify</i> ):   |

**Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE**

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

  
DAVID C. WOODCRAFT

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. ☐ The applicant has been informed accordingly.

4. ☐ The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.

5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

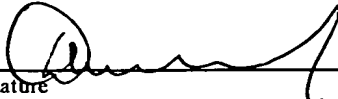
For International Bureau use only

Demand received from IPEA on:

## PCT

## FEE CALCULATION SHEET

## Annex to the Demand for international preliminary examination

International application No. <b>PCT/GB99/03392</b>	For International Preliminary Examining Authority use only	
Applicant's or agent's file reference <b>DCW/WSW</b>	Date stamp of the IPEA	
Applicant <b>KCI MEDICAL LIMITED et al</b>		
<b>Calculation of prescribed fees</b>		
1. Preliminary examination fee .....	<b>Euros 1533</b>	<div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">P</div>
2. Handling fee <i>(Applicants from certain States are entitled to a reduction of 75% of the handling fee. Where the applicant is (or all applicants are) so entitled, the amount to be entered at H is 25% of the handling fee.)</i> .....	<b>Euros 148</b>	<div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">H</div>
3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box .....	<div style="border: 1px solid black; width: 100px; height: 20px; display: flex; align-items: center; justify-content: center;">1681</div>	
	<div style="border: 1px solid black; width: 100px; height: 20px; display: flex; align-items: center; justify-content: center;">TOTAL</div>	
<b>Mode of Payment</b>		
<input checked="" type="checkbox"/> authorization to charge deposit account with the IPEA (see below)	<input type="checkbox"/> cash	
<input type="checkbox"/> cheque	<input type="checkbox"/> revenue stamps	
<input type="checkbox"/> postal money order	<input type="checkbox"/> coupons	
<input type="checkbox"/> bank draft	<input type="checkbox"/> other (specify):	
<b>Deposit Account Authorization</b> <i>(this mode of payment may not be available at all IPEAs)</i>		
The IPEA/ _____ <input checked="" type="checkbox"/> is hereby authorized to charge the total fees indicated above to my deposit account.		
<input type="checkbox"/> <i>(this check-box may be marked only if the conditions for deposit accounts of the IPEA so permit)</i> is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.		
2805.0035 Deposit Account Number	28 April 2000 Date (day/month/year)	 Signature

# PATENT COOPERATION TREATY

DCW  
4

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

## PCT

WOODCRAFT, David C. BROOKES & MARTIN High Holborn House 52/54 High Holborn London WC1V 6SE GRANDE BRETAGNE		<b>RECEIVED</b>  24 MAY 2000  <b>BROOKES &amp; MARTIN</b>	<b>NOTIFICATION OF RECEIPT OF DEMAND BY COMPETENT INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY</b>  (PCT Rules 59.3(e) and 61.1(b), first sentence and Administrative Instructions, Section 601(a))
		Date of mailing (day/month/year)	22.05.00
Applicant's or agent's file reference DCW/SH		<b>IMPORTANT NOTIFICATION</b>	
International application No. PCT/GB 99/03392	International filing date (day/month/year) 13/10/1999	Priority date (day/month/year) 13/10/1998	
Applicant  KCI MEDICAL LIMITED et al.			

1. The applicant is hereby notified that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

02/05/2000

2. This date of receipt is:

- ☒ the actual date of receipt of the demand by this Authority (Rule 61.1(b)).  
☐ the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).  
☐ the date on which this Authority has, in response to the invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3. ☐ **ATTENTION:** That date of receipt is **AFTER** the expiration of 19 months from the priority date. Consequently, the election(s) made in the demand does (do) not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22). For details, see the *PCT Applicant's Guide*, Volume II.

- ☐ (If applicable) This notification confirms the information given by telephone, facsimile transmission or in person on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA:

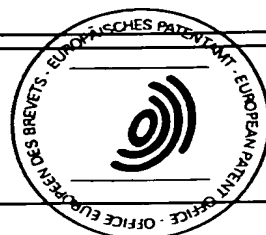


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cord 19/9/00  
PCT COOPERATION TREATY

DCW

From the:  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

5

To:  
WOODCRAFT, David C.  
BROOKES & MARTIN  
High Holborn House  
52/54 High Holborn  
London WC1V 6SE  
GRANDE BRETAGNE

24 JUL 00

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing (day/month/year)		19.07.2000
Applicant's or agent's file reference DCW/SH		REPLY DUE within 3 month(s) from the above date of mailing
International application No. PCT/GB99/03392	International filing date (day/month/year) 13/10/1999	Priority date (day/month/year) 13/10/1998
International Patent Classification (IPC) or both national classification and IPC A61M1/00		
Applicant KCI MEDICAL LIMITED et al.		


- This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:
  - ☒ Basis of the opinion
  - ☐ Priority
  - ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Lack of unity of invention
  - ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Certain document cited
  - ☒ Certain defects in the international application
  - ☒ Certain observations on the international application
- The applicant is hereby **invited to reply** to this opinion.
 

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also:** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6.

**If no reply is filed,** the international preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 13/02/2001.

Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer / Examiner Fontenay, P
	Formalities officer (incl. extension of time limits) Edel, M Telephone No. +49 89 2399 2426



**I. Basis of the opinion**

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

**Description, pages:**

1-7 as originally filed

**Claims, No.:**

1-11 as originally filed

**Drawings, sheets:**

1/3-3/3 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

3. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	8-11
Inventive step (IS)	Claims	1-7
Industrial applicability (IA)	Claims	

**2. Citations and explanations**

**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item V** Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 = WO-A-9718007

D2 = US-A-5669892

D2 was not cited in the International Search Report. A copy is annexed to the present communication.

**V.1** The subject-matter of claims 8-11 is not new in the sense of Article 33(2) PCT.

V.1.1 Document D1 discloses an apparatus for applying negative pressure therapy to a wound site (see D1, page 1, lines 2 and 3). Said apparatus comprises an open celled foam pad (102) for application to the wound (see D1, page 9, third paragraph); a suction tube connecting the foam pad to a collection canister (100) and a tube (103) for connecting the canister to a pump (6) (see D1, page 5, lines 17-26). It is also noted that said means for connecting to a pump are also adapted for connecting to a wall suction point or a vacuum bottle by eventually providing the appropriate connecting tubes. The apparatus disclosed in D1 also comprises means (105) for sensing when the canister is full (see D1, page 6, second paragraph).

All the features of claim 8 are known in combination from D1. Claim 8 is therefore not new.

V.1.2 The apparatus of D1 further includes means for giving a warning that the canister is full (claim 9 - see D1, page 6, second paragraph). Means for monitoring the pressure at the wound site are also foreseen in D1 (claim 10 - see D1, page 5, lines 24-26). The pressure between canister and the suction source can also be regulated (claim 11 - see D1, page 5, lines 25-26).

The subject-matter of claims 9-11 is therefore also not new.

**V.2** The subject-matter of claims 1-7 is not inventive in the sense of Article 33(3) PCT.

V.2.1 In addition to the features mentioned under point V.1, the apparatus disclosed in D1 also comprises a pressure detecting means (105) connected to the suction tube (103) between the foam pad and the canister for indicating when the pressure in the suction tube falls below a predetermined level (see comments under point VIII).

The subject-matter of claim 1 accordingly differs from said known apparatus only in that the canister includes a shut-off valve which closes the outlet of the canister when it is full.

The problem to be solved by said features is to provide an alternative to the apparatus disclosed in D1 in which the working of the pump is automatically shut off.

It is however considered that it is common practise in hospitals today to associate suction lines with shut-off valves in order to avoid contamination of the hospital suction systems. The skilled man would accordingly incorporate a shut-off valve in his apparatus if he intends to connect it to an external suction line, without exercising any inventive skills. The applicant may for example refer to document D2, column 1, lines 31-39.

The subject-matter of claim 1 is therefore not inventive.

V.2.2 The features of dependent claims 2-7 are disclosed in relation with similar wound suction apparatuses known from the prior art as indicated in the International Search Report. It would accordingly be obvious for the skilled man to consider the teaching of said documents and to incorporate said features to the device of D1. The applicant may refer to the Guidelines, PCT/GL/3, § 8.8(B1)).

The dependent claims 2-7 therefore do not appear to contain any additional features which, in combination with the features of claim 1 to which they refer, involve an inventive step.

**Re Item VII** Certain defects in the international application

**VII.1** Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D2 is not mentioned in the description, nor is this document identified therein.

**VII.2** Independent claim(s) should be drafted in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate.

**VII.3** The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

**VII.5** The application documents should be self-contained. The applicant should refer to the Guidelines PCT/GL/3, Chapter II, § 4.17. In present case, the wording "incorporated therein" as it appears on page 5, line 5 should be deleted.

**VII.6** A reference to non published applications should be replaced by a reference to the publication number (this applies to the US application which is not published as such).

**VII.7** Reference in claim 6 to claim 6 should be corrected. Reference to relief valve "24" on page "24" should probably be replaced by a reference to relief valve "11". Reference "15" could not be found in the drawings (see page 6, line 7).

**Re Item VIII** Certain observations on the international application

**VIII.1** The subject-matter of claim 1 is not clearly defined (Article 6 PCT).

The wording "for indicating when the pressure in the suction tube falls below a predetermined level" is ambiguous because it suggests that the pressure drops whereas according to the description, the temperature increases and tends to reach the atmospheric pressure. The applicant should have clearly defined that the relative negative pressure is meant.

**WRITTEN OPINION  
SEPARATE SHEET**

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International application No. PCT/GB99/03392

**Comments:**

The applicant may file possible amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate.

Moreover, the applicant's attention is drawn to the fact that, as a consequence of Rule 66.8(a) PCT the examiner is not permitted to carry out any amendments under the PCT procedure, however minor these may be.

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

From the INTERNATIONAL SEARCHING AUTHORITY

**PCT**

To:  
BROOKES & MARTIN  
Attn. Woodcraft, David C.  
High Holborn House  
52/54 High Holborn  
London WC1V 6SE  
UNITED KINGDOM

RECEIVED

11 FEB 2000

BROOKES &amp; MARTIN

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT  
OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing  
(day/month/year)

09/02/2000

Applicant's or agent's file reference

DCW/SH

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/GB 99/ 03392

International filing date  
(day/month/year)

13/10/1999

Applicant

KCI MEDICAL LIMITED et al.

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

**Where?** Directly to the International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland  
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the International application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the International application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for International publication.

Within 19 months from the priority date, a demand for International preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+31-70) 340-3018

Authorized officer

Nathalie Geisler



These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

## INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

### What documents must/may accompany the amendments?

#### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

**"Statement under article 19(1)" (Rule 46.4)**

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

**It must be in the language in which the international application is to be published.**

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

**Consequence if a demand for international preliminary examination has already been filed**

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

**Consequence with regard to translation of the international application for entry into the national phase**

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.